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## **Management of MDR-TB from a human rights perspective: obligations of states under international human rights law**

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REGIONAL OFFICE FOR

**World Health  
Organization**

**Europe**

# **Tuberculosis, ethics and human rights**

Report of a regional workshop

WHO Regional Office for Europe  
Copenhagen, Denmark  
16 October 2013

## ABSTRACT

The *Consolidated action plan to prevent and combat multidrug- and extensively drug-resistant tuberculosis in the WHO European Region, 2011-2015* raises important ethical, human-rights and legal issues that need to be addressed. In 2010, WHO developed guidance on the ethics of tuberculosis prevention, care and control and, more recently, the Global Fund to Fight AIDS, Tuberculosis and Malaria published a strategic plan on the promotion and protection of human rights. The objectives of the Regional workshop on tuberculosis, ethics and human rights held at the WHO Regional Office for Europe on 16 October 2013 were to afford the countries the opportunity of sharing best practices and discuss ways of solving the human-rights and ethical problems related to the involuntary isolation and/or involuntary treatment of people with TB and M/XDR-TB and the compassionate use of new drugs. The workshop concluded that: involuntary treatment is not acceptable for any TB and M/XDR-TB patient; the involuntary isolation of TB patients should be considered as a last resort and only when other measures, such as decentralized treatment and adequate patient support, have failed; during the assessment of a patient in connection with possible involuntary isolation, consideration should be given to related country-specific requirements; WHO assistance would be required in a number of areas related to involuntary isolation; the compassionate use of new anti-TB drugs should be considered an urgent need in WHO European countries with a high burden of MDR-TB and XDR-TB; and that WHO assistance would be requested in a number of areas pertaining to the compassionate use of these drugs.

## KEYWORDS

ETHICS

HUMAN RIGHTS

TUBERCULOSIS, MULTI-DRUG RESISTANT

TUBERCULOSIS, EXTENSIVELY DRUG-RESISTANT

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## **Annex 3. Management of MDR-TB from a human-rights perspective: obligations of states under international human-rights law**

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### **1. Introduction**

Public health ethics and human rights share common goals, namely, the protection of individual rights and the protection of the public, which constitute a collective benefit. These values have to be safeguarded, which implies the necessity of balancing individual rights on one hand and protecting the public on the other.

Guarantees of human rights may sometimes conflict with the mechanisms used and decisions taken in connection with diagnosing, treating and controlling MDR and XDR-TB. One example of such a conflict is when the detection of cases of MDR and XDR-TB occasions the implementation of extraordinary control measures, such as detention, quarantine or forced treatment, which usually constitute an infringement of a person's right to liberty and security.

The human rights most relevant to this discussion are: the right to life; the right to liberty and security; the right not to be subjected to torture or to inhuman or degrading treatment or punishment; the right to respect for private life and physical integrity; and the right to health.

### **2. International human-rights law**

Each of these rights is enshrined in international and regional treaties. One of the most significant sources of international human-rights law is the Universal Declaration of Human Rights (UDHR) adopted in 1948 by the General Assembly of the United Nations (*a*). This declaration has inspired the content of many other treaties adopted within the framework of the United Nations or at the regional level within the framework of other organizations, such as the Council of Europe. The most relevant human-rights treaties are: the International Convention on the Elimination of All Forms of Racial Discrimination (ICERD) (*b*), the International Covenant on Civil and Political Rights (ICCPR) (*c*), the International Covenant on Economic Social and Cultural Rights (ICESCR) (*d*), the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW) (*e*), the Convention on the Rights of the Child (CRC) (*f*), the Convention on the Rights of Persons with Disabilities (*g*); and, at the regional level, the European Convention on Human Rights (ECHR) (*h*).

Armenia, Azerbaijan, Belarus, Estonia, Georgia, the Republic of Moldova, the Russian Federation and Ukraine, are among the countries the States Parties to the above-mentioned international treaties. With the exception of Belarus, these countries are Member States of the Council of Europe and, as such, party to ECHR (*h*) and the European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (*i*).

The obligations<sup>10</sup> of states parties take different forms, which are:

- (i) to respect rights by desisting from passing laws that are, for example, discriminatory;
- (ii) to protect the individuals in their territory and subject to their jurisdiction from violations perpetrated by third parties; and
- (iii) to fulfil rights by taking active steps to deliver their obligations (*j*).

### 3. Detention

The detention of patients for the management and control of infectious diseases implies quarantine, isolation and other well known public health tools.

Isolation is defined in IHR, Article 1 as the “separation of ill or contaminated persons or affected baggage etc. (...) in such a manner as to prevent the spread of infection or contamination” (*k*). In the same article, quarantine is defined as the “restriction of activities and/or separation from others of suspect persons who are not ill, or of suspect baggage, containers, conveyances or goods in such a manner as to prevent the possible spread of infection or contamination” (*k*).

Detention is a violation of ICCPR, Article 9 (*c*), which guarantees everyone’s right to liberty and security of person, as well as of ECHR, Article 5 (*h*).

However, although the right to liberty is of profound importance, it is not absolute. ICCPR, Article 9 (*c*), and ECHR, Article 5 (*h*), do not exclude arrest or detention. They do, however, require that deprivation of liberty is non-arbitrary and carried out in accordance with the rule of law.

Although ICCPR, Article 9 (*c*), does not enumerate reasons to justify the deprivation of a person’s liberty, involuntary hospitalization in the case of infectious diseases is interpreted in ICCPR as a deprivation of liberty (*l*).

ECHR (*h*) however, does list reasons permitting the deprivation of liberty; Article 5, paragraph 1 (*e*) states:

*Everyone has the right to liberty and security of person. No one shall be deprived of his liberty save in the following cases and in accordance with a procedure prescribed by law: (...) (e) the lawful detention of persons for the prevention of the spreading of infectious diseases, of persons of unsound mind, alcoholics or drug addicts or vagrants.*

Article 9 of ICCPR (*ref*), lists the following conditions to be fulfilled regarding detention in order not to violate human rights.

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<sup>10</sup> All branches of government and other public or governmental authorities, at whatever level, are in a position to engage the responsibility of the state.

**1. Detention should be non-arbitrary**, otherwise it will constitute a violation.

This notion is really broad and includes elements of inappropriateness, injustice, lack of predictability and violation of the due process of law. For a detention to be non-arbitrary, all of the circumstances relating to it must be reasonable and necessary. Any decision to keep a person in detention should be open to periodic review, and the length of detention should not exceed that for which the state can provide appropriate justification.

**2. Detention should be prescribed by law.** Unlawful detention is also a violation.

The substantive and procedural grounds for arrest and detention must be prescribed by law and should be clearly and unambiguously defined. Regulations should also provide for the possibility of a judicial review of decisions on cases involving the forcible detention of patients.

In 2005, in the case of *Enhorn v. Sweden (m)*, the European Court of Human Rights decided that a limitation of ECHR, Article 5 (*h*), would not result in a violation of the Convention (*h*) if the limitation were necessary in a democratic society and, at the same time, proportionate (*m*). The Court explained that executing the deprivation of liberty in conformity with national law does not suffice alone. The circumstances must be such that deprivation of liberty is necessary for the protection of society and the individual. The Court insists on balancing the rights of society with those of the individual. According to the Convention (*h*), the predominant reason for depriving a person of his/her liberty is not only the fact that the person is a danger to public safety but also the fact that detention may be necessary in the person's own interest.

**4. Compulsory treatment**

According to international human-rights law, medical treatment should not be administered without consent. This principle is enshrined in different human rights guaranteed under ICCPR (*c*), ICESCR (*d*) and ECHR (*h*), such as the right to self-determination and autonomy (ICCPR, Article 1 (*c*)); the right not to be subjected to torture or to inhuman or degrading treatment (ICCPR, Article 7 (*c*)); ECHR, Article 3 (*h*)); the right to the security of the person (ICCPR, Article 9 (*c*)); the right to physical integrity (ICCPR, Article 17 (*c*); ECHR, Article 8 (*h*)); and the right to health (ICESCR, Article 12 (*d*)).

ICESCR, Article 12 (*d*) interprets the right to health to include freedom and entitlements and defines freedom as having “the right to control one's health and body (...) and the right to be free from interference, such as the right to be free from (...) nonconsensual treatment (...) (*j*).”

However, this principle is not absolute. Two exceptions are recognized: (1) “... for the treatment of mental illness, or (2) “the prevention and control of communicable diseases” (*j*). The Committee reiterated that compulsory treatment is acceptable on an exceptional basis.

The European Court of Human Rights confirmed this interpretation, for example, in connection with the case of *Acmanne and others v. Belgium in 1984 (n)*. Interference with an individual's

freedom of choice within the sphere of health care must be prescribed by law and can only be justified if it is “necessary in a democratic society” and proportionate.

## 5. Compassionate use

According to European legislation: “compassionate use” shall mean “making an unauthorized medicinal product (...) available for compassionate reasons to a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who can not be treated satisfactorily by an authorised medicinal product” (o).

National legislation on compassionate use is extremely varied around the world. Some countries do not foresee the possibility of accessing unauthorized drugs while others have a more or less restrictive system. Member States of the European Union are under no obligation to adopt legislative acts enabling compassionate use.

From a human-rights perspective, it is relevant to question:: (1) whether access to drugs, which are not on the market for terminally ill patients, is a human-rights requirement; and (2) whether it would be positive to oblige countries to enable access to drugs, which have not been fully tested for safety and efficacy, in certain circumstances.

So far, the European Court of Human Rights has dealt with one case on compassionate use, namely that of *Hristozov and others vs. Bulgaria* (p). The applicants, who were suffering from various types of terminal cancer, wished to be treated by means of the compassionate use of an anti-cancer drug that a Canadian developing company would provide free of charge. The Bulgarian authorities, in accordance with the national legislation, refused to grant access to this drug. Bearing in mind that matters of health-care policy are normally dealt with by the national authorities (p),<sup>11</sup> the Court was very cautious in its deliberations and concluded that the Convention had not been violated. More specifically, the Court, while acknowledging that “acts and omissions of the authorities in the field of health care policy may in some circumstances engage the state’s responsibility under ECHR, Article 2” (p),<sup>12</sup> refused to derive from this that the State was under any obligation to regulate in a certain way to allow access to unauthorized drugs. Moreover, the Court considered that the balance between the competing interests of the public to access safe medicinal products on one hand, and the interest of terminally ill patients in obtaining access to experimental products on the other, was acceptable with respect to the wide margin of appreciation in this field afforded to national authorities (p).<sup>13</sup>

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<sup>11</sup> *Judgment Hristozov and others vs. Bulgaria*, § 119. (p).

<sup>12</sup> *Judgment Hristozov and others vs. Bulgaria*, §§ 106-109 (p).

<sup>13</sup> *Judgment Hristozov and others vs. Bulgaria*, §§ 121-126 (p).

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